PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P200301630WO	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/DK2004/000787	International filing date *(day/month/year)* 12.11.2004	Priority date *(day/month/year)* 14.11.2003
International Patent Classification (IPC) or national classification and IPC INV. B29C45/26 A61M25/00		
Applicant UNOMEDICAL A/S		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 4 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in celectronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
23.06.2005	08.03.2006
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Zattoni, F Telephone No. +31 70 340-3202

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/DK2004/000787

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   Description, Pages

   1-13 as originally filed

   Claims, Numbers

   1-22 received on 23.06.2005 with letter of 23.06.2005

   Drawings, Sheets

   1/3-3/3 as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

   * *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-22
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-22
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-22
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following document:

   D1: WO-A-9000960

2.1 Document D1, cf. figure 2, discloses a method for one-piece injection moulding of a soft needle catheter to be inserted by an introducer needle, which cathether comprises a hub (12,13) and a tube-shaped flexible part (11) comprising the steps of feeding a molten polymer into a mould comprising a core defining a cavity composed of a hub cavity and a tube shaped cavity, said core having a cone-shaped part (defining elements 12 and 13 in D1) and a cylindrical part (defining element 11 in D1) forming the interior of the catheter; removing the core from the catheter when the polymer has been cured; removing the catheter from the mould.

Claim 1 differs therefrom in that a core is used wherein the cone-shaped part of the core forms at least a part of the interior of the hub and extends into the tube-shaped cavity so as to form an interior of the tube-shaped flexible part being at least partially cone-shaped.

The subject-matter of claim 1 is therefore new in the sense of Article 33(2) PCT.

The objective-problem underlying claim 1 is to provide a method of producing a catheter with a thin walled tube without having to use a sleeve moving between the mould and the core with great precision.

The combination of features of claim 1 is not disclosed nor suggested by the available prior art documents and claim 1 also meets the requirements of Article 33(3) PCT.

2.2 Similar as what brought forward for claim 1 applies correspondingly for the combinations of feaures of independent product claim 11 and apparatus claim 21.

Claims (amended 21 June 2005)

1. A method for one-piece injection moulding of a soft needle catheter used together with an introducer needle comprising a hub (3) and a tube-shaped flexible part (4), comprising the steps of:

- feeding a molten polymer into a mould comprising a core (9) defining a cavity composed of a hub cavity and a tube-shaped cavity, said core having a cone-shaped part and a cylindrical part (5) forming the interior of the catheter;
- removing the core from the catheter when the polymer has been sufficiently cured for the core to be removed; and
- removing the catheter from the mould when the polymer has been sufficiently cured to be removed;

characterized in using a core (9) wherein the cone-shaped part of the core forms at least a part of the hub cavity and extends into the tube-shaped cavity causing the interior of the tube-shaped flexible part (4) to be at least partially cone shaped.

2. A method according to claim 1, wherein the catheter is cured to its final state in the mould.

3. A method according to claim 1 or 2, wherein the molten polymer is supplied to the mould via at least two inlets preferably the inlets are placed symmetrically around the axis of the core.

4. A method according to any one of claims 1 to 3, wherein the inlets are placed at the hub (3) forming part of the mould.

5. A method according to any one of claims 1 to 4, wherein the mould separates along the axis of the tube-shaped part (4).

6. A method according to any one of claims 1 to 4, wherein the mould separates perpendicular to the tube-shaped part (4) and at or just below the hub (3).

7. A method according to any one of claims 1 to 6, wherein the polymer is chosen from polyester ethers, ECDEL, styrene based TPE, olefin based TPE, urethane based TPE, ester based TPE, amid based TPE polyolefines and silicone rubbers.

8. A method according to any one of claims 1 to 6, wherein the polymer is selected from the group consisting of polypropylene, C-FLEX™, mixtures of C-FLEX™ and polypropylene, LUPOLEN™ 1840H, LUPOLEN™ 3020D, PELLETHANE ™ 2363-75D, PELLETHANE™ 2363-55D, TECOTHANE ™ and CARBOTHANE™.

9. A method according to any one of claims 1 to 8, wherein the polymer has a shore between 40 and 60D.

10. A method according to any one of claims 1 to 9, wherein more than one polymer is used in the method.

11. A soft needle catheter used together with an introducer needle comprising a hub (3) and a tube-shaped flexible part (4) having a first end and a second end, the hub and the tube-shape flexible part being in one piece and being connected at the first end of the tube-shaped flexible part, characterized in that the interior of the tube-shaped part has both a cone-shaped part and a cylindrical part (5), the cylindrical part being placed at the second end of the tube-shaped flexible part.

12. A soft needle catheter according to claim 11, wherein the hub (3) is fitted with means for assisting the removal of the catheter from the patient, preferably in form a flap, a rim or a groove.

13. A soft needle catheter according to any one of claims 11 or 12, wherein the hub (3) is fitted with at least one carving, preferably two carvings placed opposing each other.

14. A soft needle catheter according to any one of claims 11 to 13, wherein the hub (3) has means for sealing the hub to a drug delivery device, said means being provided on the outside of the hub in form of at least one round going packing, rim or fin or by having a hub with a cone shaped exterior having a size suitable to fit into a cone shaped cavity of a drug delivery device.

15. A soft needle catheter according to any one of claims 11 to 14, wherein the tube-shaped part (4) of the soft needle catheter has a ratio between the cylindrical part (5) and the cone-shaped part in the range from 10:1 to 1:40, preferably the range is from 5:1 to 1:30, more preferably the range is from 2:1 to 1:20 and most preferably from 1:1 to 1:15.

16. A soft needle catheter according to any one of claims 11 to 15, wherein the cylindrical part (5) is 1.5 mm long.

17. A soft needle catheter according to any one of claims 11 to 16, wherein the cylindrical part (5) is rounded.

18. A soft needle catheter according to any one of claims 11 to 17, wherein the polymer is chosen from polyester ethers, ECDEL, styrene based TPE, olefin based TPE, urethane based TPE, ester based TPE, amid based TPE polyolifines and silicone rubbers.

19. A soft needle catheter according to any one of claims 11 to 17, wherein the polymer is selected from the group consisting of polypropylene, C-FLEX™, mixtures of C-FLEX™ and polypropylene, LUPOLEN™ 1840H, LUPOLEN™ 3020D, PELLETHANE ™ 2363-75D, PELLETHANE™ 2363-55D, TECOTHANE ™ and CARBOTHANE™.

20. A soft needle catheter according to any one of claims 11 to 19, wherein the catheter is composed from more than one polymer.

21. A mould for producing a soft needle catheter to be used together with an introducer needle according to claim 11 comprising a hub cavity, a tube-shaped cavity and a core (9) having a cone-shaped part and a cylindrical part (5), characterized in that the cone-shaped part of the core extends into the tube-shaped cavity.

22. Use of a catheter according to any one of claims 11 to 20 intravenously or subcutaneously preferably for intravenous or subcutaneous injection of a drug.

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